

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0525]

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Agency Information Collection Activities: Proposed Collection; Comment Request; Hazard Analysis and Critical Control Point; Procedures for the Safe and Sanitary Processing and Importing of Juice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on recordkeeping requirements for applying hazard analysis and critical control point (HAACP) procedures for safe and sanitary processing for processors of fruit and vegetable juice.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20855.

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20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through

the use of automated collection techniques, when appropriate, and other forms of information technology.

Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice (OMB Control Number 0910–0466)—Extension

These regulations mandate the application of HACCP procedures to fruit and vegetable juice processing. HACCP is a preventative system of hazard control that can be used by all food processors to ensure the safety of their products to consumers. A HACCP system of preventive controls is the most effective and efficient way to ensure that these food products are safe. FDA's mandate to ensure the safety of the nation's food supply is derived principally from the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*). Under the act, FDA has authority to ensure that all foods in interstate commerce, or that have been shipped in interstate commerce, are not contaminated or otherwise adulterated, are produced and held under sanitary conditions, and are not misbranded or deceptively packaged; under 21 U.S.C. 371, the act authorizes the agency to issue regulations for its efficient enforcement. The agency also has authority under the Public Health Service Act (42 U.S.C. 264) to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State to another other State. Information development and recordkeeping are essential parts of any HACCP system. The information collection requirements are narrowly tailored to focus on the development of appropriate controls and document those aspects of processing that are critical to food safety. Through these regulations, FDA is implementing its authority under section 402(a)(4) of the act (21 U.S.C. 342(a)(4)).

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record	Total Hours
120.6(c) and 120.12(a)(1) and (b)	1,875	365	684,375	0.1	68,438
120.7, 120.10(a), and 120.12(a)(2), (b), and (c)	2,300	1.1	2,530	20	50,600
120.8(b)(7) and 120.12(a)(4)(i) and (b)	1,450	14,600	21,170,000	0.01	211,700
120.10(c) and 120.12(a)(4)(ii) and (b)	1,840	12	22,080	0.1	2,208
120.11(a)(1)(iv), 120.11(a)(2), and 120.12(a)(5)	1,840	52	95,680	0.1	9,568
120.11(b) and 120.12(a)(5) and (b)	1,840	1	1,840	4	7,360
120.11(c) and 120.12(a)(5) and (b)	1,840	1	1,840	4	7,360
120.14(a)(2), (c), and (d)	308	1	308	4	1,232
Total					358,466

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 1 provides a breakdown of the total estimated annual recordkeeping burden. The estimates in this table have been reviewed by the agency's HACCP experts, who have practical experience in observing various processing operations and related recordkeeping activities.

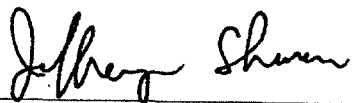
The burden estimates in table 1 are based on an estimate of the total number of juice manufacturing plants (i.e., 2,300) affected by the regulations. Included in this total are 850 plants currently identified in FDA's official establishment inventory plus 1,220 very small apple juice manufacturers and 230 very small orange juice manufacturers. The total burden hours are derived by estimating the number of plants affected by each portion of this final rule and multiplying the corresponding number by the number of records required annually and the hours needed to complete the record. These numbers were obtained from the agency's final regulatory impact analysis prepared for these regulations.

Moreover, these estimates assume that every processor will prepare sanitary standard operating procedures and a HACCP plan and maintain the associated monitoring records and that every importer will require product safety specifications. In fact, there are likely to be some small number of juice

processors that, based upon their hazard analysis, determine that they are not required to have a HACCP plan under these regulations.

Dated: 12-1-03

December 1, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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